EXHIBIT #4

Adverse Event Report

ETHICON, INC. TENSION FREE VAGINAL TAPE TVT DEVICE

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Device Problem Implant extrusion

Event Type Injury **Patient Outcome** Required Intervention;

Event Description

The complainant reports approximately 25 cases with a similar presentation and clinical course. These events have reportedly occurred over a six year period. These are pts, who following uneventful sling procedure, developed delayed failure of vaginal healing at approximately 2 months post-op, manifest in most cases as mesh palpable in the vagina by the pt, profuse discharge, contact bleeding, pain, dysuria and dyspareunia. Upon exam, pt reports these pts to have an area of exposed mesh in the midline, beneath the midurethra, in the vicinity of the original incision, measuring about 1 x 0. 5 cm. Some pts had accompanying granulation tissue. Most had well healed vaginal edges. No overt signs of infection were present. The physician performed a revision of the vaginal wound, mobilizing 0. 5cm of the vaginal wall and closing it primarily with interrupted sutures over the intact mesh. In each of these cases the revision failed within 2 weeks, requiring further surgery to excise the exposed mesh and repair the vaginal wound. In each case the second procedure was successful.

Manufacturer Narrative

B-6: the physician had pathology assessments of the excised vaginal wall tissue and found, upon h&e staining, the presence of fibrosis, granulation and plasma cell + lymphocyte infiltration. D3 and g1: since the lot number is unknown, the mfg site could be one of the following: medscand medical ab, po box 20047, malmo, sweden, 1035953; ethicon sarl, rue du puits godet 20, neuchatel, switzerland, ch-2000. D6: the exact product code involved is unknown, however, it could be 810041 or 510041. H-6 conclusion: no conclusion can be drawn at this time. Should further info be obtained, a supplemental 3500a will be submitted accordingly. The product insert, which accompanies each device, states "transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula, formation and inflammation".

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting, enter device information to search Alerts/Recalls)

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Brand Name	TENSION FREE VAGINAL TAPE
Type of Device	TVT DEVICE
Manufacturer *(Section F)*	ETHICON, INC. Route 22 West Somerville NJ 08876
Manufacturer *(Section D)*	ETHICON, INC. Route 22 West Somerville NJ 08876
Manufacturer Contact	Mark Yale Route 22 West P.O. Box 151 Somerville , NJ 08876-0151 (908) 218 -2326
Device Event Key	389932
MDR Report Key	400882
Event Key	378847
Report Number	2210968-2002-00491
Device Sequence Number	1
Product Code	FTL
Report Source	Manufacturer
Source Type	Health Professional,User facility
Reporter Occupation	Other
Type of Report	Initial
Report Date	05/20/2002
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	06/17/2002
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Was Device Available For Evaluation?	No

Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	unknown
Event Location	Unknown
Date Manufacturer Received	05/20/2002
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Is The Device Single Use?	Yes
Is the Device an Implant?	Yes
Is this an Explanted Device?	Unknown
Type of Device Usage	Initial

Database last updated on April 27, 2007
